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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/838,649

Applicant(s)

CIOCA ET AL.

Examin r

Lauren Q Wells

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-- The MAILING DATE f this communication appears on the cover sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003 .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 13-18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-12, 19-20, 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

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DETAILED ACTION

Claims 1-22 are pending. Claims 6-8, 13-18 and 21 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 6/4/03, Paper No. 7, amended claims 1-5.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-12, 19-20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "characterized by" in claim 1 (lines 3 and 4) is vague and indefinite, as the metes and bounds of the claim are unascertainable, as this phrase is not a positive recitation. Does the water always have a conductivity and pH of that recited in the claim or is it often associated (characterized by) such a conductivity and pH. This rejection can be overcome substituting the term "has" for the phrases "is characterized by" in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 4-5, 9-12, 19-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cioca et al. (6,139,855) in view of Beerse et al. (6,217,887).

The instant invention is directed to structured water comprising a cluster structure, wherein at least two antimicrobial agents are within the cluster structure, and compositions and methods thereof.

Cioca et al. teach structured water in cosmetic compositions, wherein the compositions comprise a biologically active agent. The structured water is defined as water that contains stabilized clusters of ions. The composition contains a combination of I and S water, though it is disclosed that just I water or just S water can be utilized in composition. The I water is characterized by a conductivity of about 900-2500 and pH of about 1.9-2.5, and S water is characterized by a conductivity of about 400-1500, and a pH of about 10.5-12. It is disclosed that the composition can be used to enhance the activity of antibacterial agents. Exemplified is a method of topically applying the composition to the skin and a method of adding the clustered water to a cosmetic product, such as lipstick, foundation, blush, and others. See Col. 3, lines 43-Col. 4, line 26; Col. 1, line 19-Col. 2, line 66. The reference lacks a teaching of at least two antimicrobial agents within the cluster and silver ions.

Beerse et al. teach leave-on antimicrobial compositions which provide improved immediate germ reduction. Silver is taught as an active antimicrobial agent. See Col. 7, lines 54-67.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the silver of Beerse et al. as the biologically active agent of Cioca et al. because Cioca et al. teach antibacterials as biologically active agents, whose activity can be enhanced when combined with structured water; thus, one of skill in the art would be motivated

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to combine the silver and structured water because of the expectation of achieving a topical cosmetic composition that is potent toward bacteria.

It is respectfully pointed out that a) silver must be within the cluster structure, as the electropositive charges of silver would interact with the electronegative charges within and without of the cluster structure; b) since a compound and its properties are inseparable (In re Papesch), adding the structured water of Cioca et al. to a cosmetic composition must have the property of preserving the cosmetic.

Claims 1, 3-5, 9, 11, 12, 19-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cioca et al. in view of Stroud et al. (6,231,837).

Cioca et al. teach structured water in cosmetic compositions, wherein the compositions comprise a biologically active agent. The structured water is defined as water that contains stabilized clusters of ions. The composition contains a combination of I and S water, though it is disclosed that just I water or just S water can be utilized in composition. The I water is characterized by a conductivity of about 900-2500 and pH of about 1.9-2.5, and S water is characterized by a conductivity of about 400-1500, and a pH of about 10.5-12. It is disclosed that the composition can be used to enhance the activity of antibacterial agents. Exemplified is a method of topically applying the composition to the skin and a method of adding the clustered water to a cosmetically active ingredient. See Col. 3, lines 43-Col. 4, line 26; Col. 1, line 19-Col. 2, line 66. The reference lacks a teaching of at least two antimicrobial agents within the cluster and potassium sorbate.

Stroud et al. teach cosmetic compositions. Potassium sorbate is disclosed as an antibacterial agent in cosmetic compositions. See Col. 18, lines 43-53.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the potassium sorbate of Stroud et al. as the biologically active agent of Cioca et al. because Cioca et al. teach antibacterials as biologically active agents, whose activity can be enhanced when combined with structured water; thus, one of skill in the art would be motivated to combine the potassium sorbate and structured water because of the expectation of achieving a topical cosmetic composition that is potent toward bacteria.

Response to Arguments

Applicant argues, “the Examiner finds that adding structured water taught in Cioca et al. to a cosmetic composition must have the property of preserving the cosmetic. This, Applicants believe is not an accurate depiction of the teachings of Cioca et al. because at column 2, lines 36 to 66, it is taught not that structured water preserves the composition”. This argument is not persuasive. Claim 22 is directed to a method of preserving a cosmetic or pharmaceutical composition comprising adding to the composition the structured water of claim 1. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches adding such structured water to a cosmetic composition as instantly claimed, which would inherently preserve a cosmetic as instantly claimed. Applicant has not

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provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Applicant argues, "the two antimicrobial agents are incorporated within the cluster structure of the structured water. As a result, the silver ions do not precipitate out of the structured water of the present invention. This serves as evidence of the difference between the present invention and the mere addition of silver salts added to structure water or any other types of water". This argument is not persuasive, as a mere statement is not evidence. The Examiner respectfully points out that Applicant has not provided evidence that the combination of references in the prior art does not result in the same product as instantly claims.

Applicant argues, "This is discussed in the present specification at page 1, lines 19-31. Therefore, the silver ions simply added to water does not experience the type of electrostatic interaction that would result in clusters having silver ions within them". This argument is not persuasive, as page 1, lines 19-31 of the specification is merely referring to silver in an aqueous suspension. The instant rejection specifically teaches clustered water as the medium.

Applicant argues, "The addition of silver to water, whether it be structured, tap or deionized water, is not the same as incorporation of silver ions within the clusters of structured water as set forth in the present specification at page 5, lines 20-22". This argument is not persuasive, as page 5, lines 20-22 of the specification teach a method of making the clustered water. However, such is argument is not commensurate in scope with the instantly examined claims, as the instantly examined claims are not directed toward a method of making structured water comprising silver ions.

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Applicant argues, "the cluster structure stabilizing ions have a much smaller ionic radius in comparison with the silver ion. Because of the difference in the size of the ionic radii, the silver ion would not be expected by one of ordinary skill in the art to be readily incorporated within the cluster structures of structured water when silver ion is simply added to structured water". This argument is not persuasive, as Applicant has provided no evidence to back up this statement. Because of the attraction of charges between the silver ion and the clustered water, one of skill in the art would expect that adding silver ions to clustered water would result in silver ions being incorporated within the clustered water structure.

Applicant argues, "The simple addition of ions to feed water alone does not make structured water. This is disclosed in the present specification at page 4, lines 26 to 27". This argument is not persuasive, as page 4, lines 26-27 does not make any such statement.

Applicant argues, "If, as the Examiner suggests, silver ions could simply added to the structured water and interactions took place such that the silver ions were within the clusters of structured water, one of ordinary skill in the art would expect that the integrity of the clusters would be compromised and the structured water based on a set of clusters would be broken down". This argument is not persuasive, as Applicant has provided no evidence to back up this statement.

Applicant argues, "the Beerse reference fails to disclose structured water, therefore, it alone fails to render the present invention obvious". This argument is not persuasive, as Beerse was merely relied upon to teach a specific antibacterial agent since Cioca et al. teaches that antibacterial agents can be added to their compositions.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


**RUSSELL TRAVERS
PRIMARY EXAMINER**


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lqw

July 9, 2003


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